DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 7 1996

Larry R. Pilot
McKenna & Cuneo, L.L.P.
1575 Eye Street, N.W.
Washington, D.C. 20005

Re: Docket No. 95P-0320/CCP1
Reclassification Petition
Obstetric Data Analyzers
Dated: September 22, 1995
Received: September 22, 1995
Filed: September 22, 1995

Dear Mr. Pilot:

The Food and Drug Administration (FDA) has reviewed the above mentioned petition for reclassification pursuant to section 513(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e)) and under section 515(b) of the act in response to the proposed call for premarket approval applications (PMA) for obstetric data analyzers. We have identified below the lack of certain information which prevents us from referring the petition to an advisory panel at this time.

The regulations governing reclassification of medical devices are included in the Medical Device Classification Procedures, Part 860 of Title 21, Code of Federal Regulations (21 CFR 860). Reclassification is specifically addressed in Subpart C, sections 860.120 through 860.136. A copy of Part 860 is enclosed with this letter. Note the definitions in section 860.3, the discussion of confidentiality and filing in section 860.5, the discussions of determination of safety and effectiveness and of valid scientific evidence in section 860.7, and the discussion of content and form in section 860.123. All these factors bear directly on petitions for reclassification and should be well understood by all petitioners.

The following deficiencies have been identified and must be corrected before your petition can be referred to the appropriate advisory panel for review:

1. The petition must provide a specification of the type of device for which the reclassification is requested (21 CFR 860.123 (a)(1)). The description which you provided needs clarification. Many electronic fetal monitors already provide limited data analysis, such as detection of fetal tachycardia and bradycardia, with set points that can be adjusted by the attending clinician. These are considered to be class II devices (21 CFR 884.2740) and are already routinely cleared for market under 510(k) premarket notification. Further, some of these devices are described in the literature that you provided. Please provide a more detailed description of the obstetric data analyzer, including specifications, key algorithms, and the precise nature of diagnostic information displayed to the clinician.

2. The petition must provide valid scientific evidence satisfying the requirements of 21 CFR 860.7 to support reclassification of the obstetric data analyzer into class II. None of the studies that you provided from published literature show that a perinatal monitoring

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system, using a validated algorithm, can analyze real-time obstetric data, classify the clinical status, and present the clinical management options or recommendations (the fundamental purpose of an obstetric data analyzer). As stated in #1 above, analytical monitoring systems that do not make a diagnosis and do not make a patient management recommendation are already classified under 21 CFR §884.2740, as perinatal monitoring systems and accessories, and fall outside the scope of an obstetric data analyzer. Appropriate studies would also need to show that perinatal outcome was not adversely affected by the implementation of such technology. Although some of the studies you cited addressed parts of these issues, none of the studies adequately addressed these key safety and effectiveness questions.

3. The petition must provide a full statement of the reasons why the device should not be classified in its present classification (class III) and how the proposed classification (class II) will provide reasonable assurance of the safety and effectiveness of the device (21 CFR 860.123(a) (6)). You must provide data which demonstrates that there is sufficient information to establish special controls, under class II, that provide a reasonable assurance of safety and effectiveness of the device. You should propose special controls which address specific risks of the device.

4. The petition must provide representative data and information known to the petitioner to be unfavorable to the petitioner's position (21 CFR 860.123(a) (7)). No such information is included in your submission.

5. The petition must provide a summary of the new information under the section ((513(e), 514(b) or 515(b)) of the act upon which the petition is based. Please note that new information is that information which is new since the time of the initial classification in 1980.

If you submit information which corrects all of the deficiencies noted above, we will refer your petition to the appropriate advisory panel for review and recommendation.

Any response, including information which corrects all the deficiencies noted above, should reference the above docket number and should be submitted in an original and two copies to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Standards and Regulations (HFZ-84)
5600 Fishers Lane
Rockville, Maryland 20857

If you have questions regarding these procedures, please contact Joseph M. Sheehan at (301) 594-4765 extension 157, or at the above address.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure